K071377

AUG - 6 2007

Section 5: 510(k) Summary

Preparation Date: August 1, 2007

Applicant/Sponsor: Biomet Spine (formally EBI Spine)
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Debra Bing
Director of Regulatory Affairs
Biomet Spine

Proprietary Name: Polaris™ BE Rods

Common Name: Spinal Rods

Classification Name: Application, Fixation, Spinal Interlaminal (87 KWP)
Orthosis, Spinal Pedicle Fixation (MNI)
Orthosis, Spondylosthesis Spinal Fixation (MNH)
Orthosis, Spinal Pedicle Fixation, for Degenerative Disc Disc Disease (NKB)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K940631 Synergy™ Spinal System (Interpore Cross, Inc.*)
K950099 Synergy™ Ti Posterior Spinal System (Interpore Cross, Inc. *)

Device Description: The Polaris™ BE Rods are manufactured from CP titanium or stainless steel in a diameter of 6.35mm. Two styles of rods are available, double bullet-ended and single bullet-ended where the opposite end is blunt like standard rods. This tip design facilitates the use of an intrasacral surgical technique (Jackson Intrasacral Fixation Technique). Lengths vary from 6 to 60cm.

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* Interpore Cross, Inc. is now a Biomet Company

Intended Use:

INDICATIONS-FOR-USE

The **SYNERGY** Spinal System implants are intended to be used as a temporary construct that assists normal healing and are not intended to replace normal body structures. They are intended to stabilize the spinal operative site during fusion procedures and should be removed after fusion.

The implants are attached to the spine posteriorly by means of hooks and/or screws joined with rods and anteriorly by means of vertebral screws joined with rods.

As a pedicle screw system the **SYNERGY** Spinal System is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the screws fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. The levels of screw fixation are L3 to S1/Ilium.

In addition, the pedicle screw system may also be used to provide immobilization and stabilization of spinal segments, in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

As a posterior, non-pedicle, screw and hook system, and an anterolateral, intervertebral body screw system, the specific indications for the **SYNERGY** Spinal System are:

1. Degenerative Disc Disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
2. Idiopathic scoliosis.
3. Kyphotic deformities of the spine.
4. Paralytic scoliosis and/or pelvic obliquity.
5. Lordotic deformities of the spine.
6. Neuromuscular scoliosis associated with pelvic obliquity.
7. Vertebral fracture or dislocation.
8. Tumors.

9. Spondylolisthesis.
10. Stenosis.
11. Pseudarthrosis.
12. Unsuccessful previous attempts at spinal fusion.

For posterior, non-pedicle, screw use, the **SYNERGY** screws and lateral connectors are intended for sacral/iliac attachment only, and the **SYNERGY** hooks and transverse connectors are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use are T1 to the Sacrum/Ilium.

The Bullet End Rods are intended for use with the Jackson Intrasacral Fixation Technique.

The Adjustable Length Rod is intended for in situ adjustment after placement of the hooks or screws during spinal fusion surgery.

For anterior use, the recommended levels of attachment are: T10 to L3 for the double rod constructs and T5 to L5 for the single rod constructs. The 4.75 mm diameter rod system can be used in single and double rod constructs while the 6.35 mm diameter rod system is to only be used in single rod constructs. In all cases, instrumentation must be at least 1 cm from any major vessel.

Summary of Technologies: The technological characteristics (materials, design, sizing, indications) of the Polaris™ BE Rods are similar to or identical to the predicate devices.

Non-Clinical Testing: Because the Polaris™ BE Rods are identical in material, diameter and minimum and maximum length, they can be expected to perform mechanically in the same manner as the predicates. An engineering rationale is provided.

Clinical Testing: No clinical testing is necessary for a determination of substantial equivalence. However, a paper containing retrospective outcome data for intrasacral rod fixation is provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2007

Biomet Spine (Former EBI Spine)
% Ms. Debra Bing
Director of Regulatory Affairs
100 Interpace Parkway
Parsippany, NJ 07054

Re: K071377
Trade/Device Name: Polaris™ BE Rods
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, KWP, MNI, MNH
Dated: May 16, 2007
Received: May 17, 2007

Dear: Ms. Debra Bing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use

510(k) Number (if known): K071377

Device Name: Polaris™ BE Rods

INDICATIONS-FOR-USE

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11. Pseudarthrosis.
12. Unsuccessful previous attempts at spinal fusion.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K071377

K071377 Indications for Use (continued)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhouse

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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